

EEL Rupture (18) Normal EEL (21) P value

Plaque Neovessels (total count)	52 ± 32	25 ± 20	0.004
Neointimal Area (mm ²)	2.4 ± 1.4	1.5 ± 1	0.037
Lumen Area (mm ²)	1.6 ± 0.7	2.5 ± 0.9	0.001
EEL Area (mm ²)	4.76 ± 1.2	4.88 ± 1.3	0.7

1149-195

Physiologic Assessment of Serial Lesions: Comparison of Present Methodologies

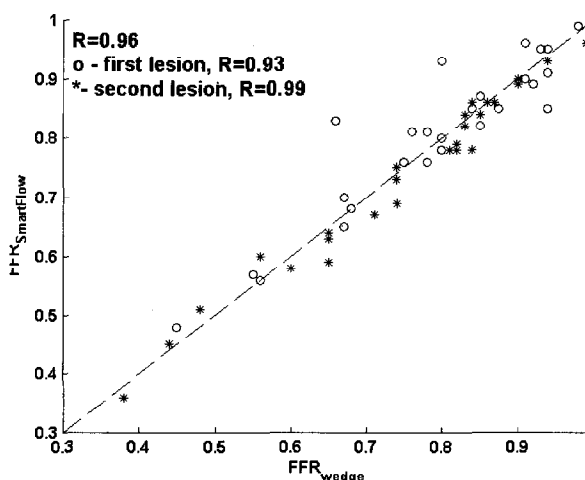
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Background: FFR is a well-established hemodynamic parameter for physiological assessment of the severity of a single coronary lesion. We compared a novel algorithm to assess the individual FFR of each lesion in a vessel with serial lesions to the current method which requires multiple hyperemic injections and wedge pressure measurements.

Methods: 26 patients undergoing intervention for two (n=24) or three (n=2) tandem lesions were studied. Basal and hyperemic pressure curves were measured distal to each of the serial stenoses. At least one lesion was treated in each patient based on angiographic evaluation. Wedge pressure was measured during balloon inflation for treatment of one of the lesions and used to calculate the wedge based value of FFR (FFR_{wedge}). FFR_{smartflow} was derived from rest pressure across each of the serial lesions and one hyperemic pressure across all lesions.

Results: Individual FFR obtained by both methods were highly correlated (r=0.96, p<0.001). The correlation was significant for both the proximal lesion (r=0.93, p<0.001) and for the distal lesion (r=0.99, p<0.001). Combining the proximal and distal lesions, there was no significant difference between the two methods (p=0.733).

Conclusions: FFR_{smartflow} allows real-time and accurate evaluation of lesion specific FFR in vessels with multiple serial lesions with only baseline pressure measurements between lesions and one distal measurement with adenosine injection.



1149-196

The Importance of Combined Pressure and Flow Velocity Measurements to Evaluate the Hemodynamic Effect of Percutaneous Coronary Interventions

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Background: We simultaneously assessed distal flow velocity (v) and pressure with a novel 0.014" dual-sensor guide wire to determine the magnitude and sequence of hemodynamic changes that contribute to the outcome of percutaneous coronary intervention (PCI).

Methods: Aortic pressure, v, and distal pressure were measured after an i.c. bolus of adenosine in 12 patients with a single de novo lesion (58.4 ± 12.5% diameter stenosis) before and after stepwise executed PCI (balloon angioplasty, stenting and upsized stenting guided by intravascular ultrasound). Pressure gradient (ΔP = aortic-distal pressure) and v at maximal hyperemia were compared per intervention step, as well as descriptors of functional stenosis severity, i.e., fractional (FFR) and coronary (CVR) flow reserve, and hyperemic stenosis resistance index (SRV=ΔP/v).

Results: An initial large decrease in ΔP was followed by non-significant changes. In contrast, v continued to increase significantly after the initial step. Upsized stenting caused variable results and slightly reduced CVR. Pressure-based parameters were least sensitive after the initial dilation, while SRV combined the sensitivity of ΔP and v for all steps of PCI-induced hemodynamic changes.

Conclusion: Stepwise executed PCI affects ΔP and v to variable degrees, with changes in pressure-based variables diminishing quickly. Assessment of PCI in hemodynamic terms benefits from combining pressure and velocity information and SRV may thus provide a valuable prognostic tool.

*p<0.05, †p<0.01 (unpaired t-test, compared to previous step)

	ΔP (mmHg)	v (cm/s)	FFR	CVR	SRV(mmHg/cm/s)
Pre-PCI	35.6 ± 16.6	30.3 ± 18.5	0.62 ± 0.17	1.86 ± 0.54	2.05 ± 2.17
Balloon	18.1 ± 9.0†	44.6 ± 11.2†	0.80 ± 0.10†	2.14 ± 0.36*	0.46 ± 0.31†
Stent	11.2 ± 7.9	59.1 ± 19.0*	0.88 ± 0.09	2.88 ± 0.62†	0.22 ± 0.19*
UPstent	11.2 ± 3.3	61.6 ± 20.3	0.88 ± 0.11	2.78 ± 0.40	0.21 ± 0.25

POSTER SESSION

1150 Novel Stent Designs and Coatings

Tuesday, April 01, 2003, 9:00 a.m.-11:00 a.m.

McCormick Place, Hall A

Presentation Hour: 9:00 a.m.-10:00 a.m.

1150-178

First Clinical Experience With 17- Estradiol-Eluting Biodivysio Matrix LO Stent to Prevent Restenosis in De-Novo Native Coronary Arteries: Six-Month Clinical Outcomes and Angiographic Follow-Up From the EASTER Trial

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Background: A recent study in the porcine coronary model demonstrated that 17-β estradiol-eluting stents reduce neointimal formation by 40%. Whether 17-β estradiol has a similar vasculoprotective effect in the clinical setting is not known.

Objective: To determine the safety of 17-β estradiol-eluting PC-coated stent (Biodivysio™) in the treatment of *de novo* native coronary stenosis; and the efficacy of this strategy on 6-month binary restenosis and late loss as assessed by angiography.

Methods: Thirty patients were studied in this prospective pilot registry. All patients received a single 15 or 18 mm drug-eluting Biodivysio™ stent. The average drug concentration was approximately 2.54 μg/mm² as previously studied in the animal model.

Results: Mean age was 61±12 years, 70% were men, 10% diabetics, 27% had hypercholesterolemia, and 44% previous MI. Lesion length was 9.1±2.4mm, and reference vessel diameter was 2.76±0.56mm. Angiographic results are shown in table:

	Post intervention	In-stent	In-segment
- MLD (mm)		2.44 ± 0.52	2.04 ± 0.43
- Diameter stenosis (%)		13.6 ± 10.4	23.4 ± 10.9
Follow-up			
- MLD (mm)		1.89 ± 0.57	1.76 ± 0.56
- Diameter stenosis (%)		28.2 ± 14.8	30.5 ± 14.9
- Late loss (mm)		0.54 ± 0.44	0.31 ± 0.38

Binary restenosis occurred in 2 pts (6.6%) and ischemic driven target vessel revascularization in one (3.3%) with no additional major adverse cardiac events

Conclusion: The implantation of 17-β estradiol-eluting Biodivysio™ stent was safe and associated with low binary restenosis and clinical recurrence. These data support the antiproliferative properties of estrogen and warrant further investigation in a larger randomized trial.

1150-179

Estradiol Coated Stents for the Prevention of Restenosis in Native Coronary Arteries: Results From the Randomized Multicentric Study EASTER

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Introduction: In vitro and animal models indicate that 17β-estradiol inhibits intimal smooth muscle cell proliferation and migration and accelerates re-endothelialization after PTCA. This study prospectively and randomly compares stents loaded with 17β-estradiol (Biodivysio DD Matrix, Biocompatibles, Galway, Ireland) to bare metal stents (Biodivysio OC) in reducing restenosis rate. **Methods:** we report the in-hospital and 1-month follow-up (FU) results of the 2 different type of stents in *de novo* lesions located on native coronary arteries. In the study 81 patients with 111 lesions 54 (48%) in the estrogen arm and 57 (52%) in the control arm. Complex lesions (B2, C type ACC/AHA) were 42% and 44% in the estrogen and in the control arm respectively (p=n.s.). No statistically significant differences were noted between the 2 groups in baseline angiographic measurements (basal ref. diam. 2.89±0.60 mm vs 2.95±0.57 mm; MLD 0.97±0.61 mm vs 1.02±0.58 mm; lesion length 11.7±8.5 mm vs 13.9±9.6 mm in the estrogen and in the control group respectively), nor after stenting (Final MLD 0.97±0.61 mm vs 1.02±0.58 mm in the estrogen and in the control group respectively). After discharge, all patients have been